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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,810	09/19/2006	David L. Kaplan	108341-6	4571
21125 7590 05/29/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER MACAULEY, SHERIDAN R	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 05/29/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/536,810

Applicant(s)

KAPLAN ET AL.

Examiner

SHERIDAN R. MACAULEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-123, 125-138, 140-146, 156, 157, 159-165 and 170 is/are pending in the application.
- 4a) Of the above claim(s) 135, 137, 138, 140-146 and 152-165 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-123, 125-134, 136 and 170 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A response and amendment have been received and entered on December 1, 2008. Claims 1-118, 124, 139, 147-155, 158 and 166-169 are cancelled. New claim 170 has been added. Claims 119-123 and 125-138, 140-146, 156, 157, 159-165 and 170 are pending. Claims 135 and 137, 138, 140-146, 156, 157 and 152-165 have been withdrawn from further consideration due to a previous requirement for restriction. Claims 119-123, 125-134, 136 and 170, insofar as they read upon the elected species, are examined on the merits in this office action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 119-123, 125-127, 129-134, 136 and 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuczkowski (Rubber Chemical Technology, 1984, 621-651, cited in previous action) in view of Miyamoto et al. (JP 5-331157, 1993; see English abstract) and Kobayashi (Chem. Rev. 2001, 101:3793-3818, cited in previous action). Claim 119 recites a method for enzymatically synthesizing a functionalized polymer comprising: enzymatically coupling an antioxidant to each of a plurality of molecules to form antioxidant-coupled monomers capable of forming an antioxidant-coupled functionalized polymer; and, enzymatically polymerizing the antioxidant-

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coupled monomers to form the antioxidant-coupled functionalized polymer; whereby the resultant functionalized polymer has inherent antioxidant capabilities. Claim 120 and 121 recite the method of claim 119, wherein the step of coupling an antioxidant to each of a plurality of molecules is carried out such that the resultant polymer has at least 1%, or 10%, of its monomeric units functionalized with antioxidants. Claim 122 recites the method of claim 119, wherein the method further comprises coupling at least one antioxidant per monomer. Claim 123 recites method of claim 119, wherein the method further comprises using a vinyl monomer. Claims 125-127 recite the method of claim 124, wherein the step of coupling an antioxidant to each of a plurality of molecules further comprises selectively acylating primary hydroxyl groups, wherein the method further comprises enzymatically coupling a primary hydroxyl group of the antioxidant to a molecule, or wherein the step of enzymatically coupling an antioxidant to each of a plurality of molecules further comprises selecting an enzyme from the group consisting of proteases, glycosidases, and lipases. Claims 129 and 130 recites the method of claim 119 wherein the antioxidant is ascorbic acid, specifically wherein the step of coupling an antioxidant to each of a plurality of molecules further comprises coupling ascorbic acid to the molecules. Claim 131 recites the method of claim 119, wherein the method of enzymatically polymerizing the antioxidant-coupled monomers further comprises using horseradish peroxidase (HRP). Claims 132 and 133 recite the method of claim 119, wherein the method further comprises casting the polymer into a shaped form, specifically a film. Claim 134 recites the method of claim 119, wherein the method further comprises selecting a monomer that is biodegradable. Claim 136 recites the

method of claim 119, wherein the method further comprises selecting a single type of monomer and the step of polymerizing the antioxidant-coupled monomers into an antioxidant-coupled polymer further comprises forming an antioxidant-coupled homopolymer. Claim 170 recites that the antioxidant-coupled monomers of claim 119 comprise at least one vinyl monomer.

6. Kuczkowski teaches a method for the production of a functionalized polymer with antioxidant capabilities wherein the antioxidant is coupled to a monomer (a vinyl; p. 628, par. 2 and following reaction scheme). The reference teaches that such polymers can be used to produce items such as belts (p. 621, par. 1). The reference does not specifically teach the use of an enzyme in the coupling of the antioxidant to the monomer or in the polymerization of the polymer.

7. Miyamoto teaches the production of an antioxidant (ascorbic acid) coupled to a vinyl monomer using an enzyme, specifically a lipase, that is capable of polymerization (see English abstract and formula 1 of document; note that R_1 can equal a hydrogen).

8. Kobayashi teaches a method for enzymatically polymerizing monomers to form polymers using horseradish peroxidase (HRP; see p. 3797, par. 1-3, for example).

9. At the time of the invention, a method for the production of an antioxidant-functionalized functionalized polymer was known in the art, as taught by Kuczkowski. It was further known in the art that monomers comprising ascorbic acid coupled to a vinyl monomer could be produced using a lipase for subsequent polymerization, as taught by Miyamoto. Polymerization of monomers using HRP was also known at the time of the invention, as taught by Kobayashi. One of ordinary skill in the art would have been

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motivated to combine the teachings discussed above because Kuczkowski teaches polymer-bound antioxidants are desirable for the production of stabilized polymers. Miyamoto discusses that monomers comprising vitamin C are desirable for polymerization. One would therefore have recognized that it would be desirable to produce a polymer-bound vitamin C using the monomers taught by Miyamoto. The use of the HRP enzyme for the synthesis polymers was also known at the time of the invention. Kobayashi teaches that the use of biological catalysts, such as HRT, for polymer synthesis is desirable because it allows for more precision in polymerization (p. 3793, par. 1-2). One of ordinary skill in the art would therefore recognize that these enzymes would be useful in the production of an antioxidant-bound polymer. The production of a polymer, specifically a homopolymer, wherein greater than 1 or 10% of the monomers are functionalized, wherein primary hydroxyl groups are acylated, or wherein a biodegradable monomer is selected, would have been a routine matter of experimentation to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching discussed above to practice the claimed invention because the synthesis steps set forth in the method were known in the art and were known to be useful with the claimed components. It would therefore have been obvious to one of ordinary skill in the art to combine the references discussed above to arrive at the claimed invention.

10. Claims 119-123, 125-134, 136 and 170 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuczkowski (Rubber Chemical Technology, 1984, 621-651,

cited in previous action) in view of Miyamoto et al. (JP 5-331157, 1993; see English abstract) and Kobayashi (Chem. Rev. 2001, 101:3793-3818, cited in previous action) as applied to claims 119-123, 125-127, 129-134, 136 and 170 above, and further in view of Yan et al. (Biotechnology Letters, 1999, 21:1051-4, cited in previous action). Claims 119-123, 125-127, 129-134, 136 and 170 are discussed above. Claim 128 recites the method of claim 124, wherein the step of enzymatically coupling an antioxidant to each of a plurality of molecules further comprises using a *Candida antarctica* lipase.

11. The teachings of Kuczkowski, Miyamoto and Kobayashi are discussed above. It would have been obvious to combine these teachings to arrive at nearly all of the elements of the claimed invention, as discussed above. None of the references, however, teaches that the step of enzymatically coupling an antioxidant to each of a plurality of molecules further comprises using a *Candida antarctica* lipase.

12. Yan teaches a method of coupling an antioxidant, specifically ascorbic acid, to a vinyl ester using *C. antarctica* lipase (CAL; abstract; p. 1052, fig. 1).

13. At the time of the invention, a method of preparing an antioxidant-coupled polymer comprising nearly all of the claimed elements was known, as taught by Kuczkowski, Miyamoto and Kobayashi. It was further known that CAL was a compatible lipase for use with ascorbic acid, as taught by Yan. One of ordinary skill in the art would have been motivated to use CAL as the lipase in the method of preparing a monomer taught by Miyamoto because the reference teaches that any lipase having ester interchange activity would have been suitable for use with the method (abstract). Yan teaches that CAL was known to be useful with esters and that the use of CAL is

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preferential to other organic synthesis reactions using ascorbic acid because it reduces the formation of undesired byproducts (p. 1051, par. 4). One would therefore have recognized that CAL would have been a useful enzyme for the preparation of an enzymatically coupled monomer, as described by the combined teachings of the prior art. One would further have had a reasonable expectation of success because Miyamoto teaches that a lipase should be used and Yan teaches a lipase that is compatible with syntheses using ascorbic acid. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

14. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

15. Applicant's arguments with respect to the rejection under 35 USC 103 in the previous office action have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is

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(571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM